UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ESPERION THERAPEUTICS, INC., Plaintiff, v. DAIICHI SANKYO EUROPE GMBH, Defendants.	No. 1:23-cv-02568-ER **DEFENDANT DAIICHI SANKYO EUROPE GMBH'S ANSWER AND AFFIRMATIVE DEFENSES TO ESPERION THERAPEUTICS, INC.'S FIRST AMENDED COMPLAINT**

Defendant Daiichi Sankyo Europe GmbH ("DSE"), by and through its undersigned counsel, submits its Answer and Affirmative Defenses to the Amended Complaint filed by Plaintiff Esperion Therapeutics, Inc. ("Esperion"). In response to the allegations in the Amended Complaint, and in support of its affirmative defenses outlined below, DSE states, upon knowledge as to itself and its conduct and upon information and belief as to all other matters, as follows:

GENERAL RESPONSE AND STATEMENT OF FACTS IN SUPPORT OF DSE'S AFFIRMATIVE DEFENSES

Esperion's Amended Complaint (Dkt. 19) gives new meaning to revisionist history. With a new management team in place (none of whom negotiated or signed the parties' License and Collaboration Agreement in 2019), Esperion resorts to fiction and mischaracterization to falsely malign its business partner and claim a large contingent milestone payment to which it is not entitled. Many paragraphs in the Amended Complaint ignore or distort the truth. As explained below, DSE will prove to this Court that the parties always intended the regulatory milestone payment at issue to require, among other things, that Esperion's CLEAR Outcome Study demonstrate at least a 15% relative risk reduction for its **primary** endpoint – the only endpoint that could on its own lead to an approved label. This is how Esperion itself designed the CLEAR

Outcome Study. It is also what Esperion emphasized when it courted DSE as a collaboration partner and it is what the parties consistently discussed during negotiations and intended when they executed the Agreement. If its allegations are accepted, Esperion's tortured interpretation of the contract would defy New York contract law, provide Esperion a gratuitous windfall that DSE never agreed to convey, and tilt the economics of the transaction upside down.

In the pharmaceutical industry, drug sponsors conduct clinical trials to determine a drug's safety and efficacy, and regulators use this data to ascertain whether the drug is worthy of approval and commercial use. In clinical trials, study investigators administer the drug being researched to human patients according to a detailed protocol. The protocol typically includes a primary endpoint that the study is designed to measure. The primary endpoint is the most important for evaluating the effect of an intervention/treatment.[1] Studies can also have non-primary endpoints, including secondary endpoints, which are by definition less important than the primary endpoint. The CLEAR Outcome Study had only one primary endpoint and several secondary endpoints.

Esperion selectively ignores the critical distinction between primary and secondary endpoints, lumping them together and claiming both should count equally for purposes of the Regulatory Milestone Payment. But by definition, and as Esperion acknowledges through its own study design, primary and secondary endpoints are not created equal, nor are they interchangeable. The primary endpoint is a study's "main research question"[2] and provides "the basis for

[1] U.S. National Library of Medicine, *Glossary of Common Site Terms*, ClinicalTrials.gov, *available at* https://clinicaltrials.gov/ct2/about-studies/glossary.

[2] McLeod C., Norman R., Litton E., Saville BR, Webb S., Snelling TL. *Choosing Primary Endpoints for Clinical Trials of Health Care Interventions*, Contemp Clin Trials Commun. (2012), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6881606/#:~:text=Primary%20endpoint(s)%20are%20typically,a%20causal%20mechanism%20%5B2%5D.

determining whether the study met its objective."[3] Secondary endpoints serve to provide data that support the primary endpoint, but unlike primary endpoints, they generally cannot on their own result in an approved drug label. These are among the reasons why secondary endpoints are less critical and carry less weight with regulators. According to regulatory guidance in Europe (where Esperion granted DSE a license), "[s]econdary endpoints may provide additional clinical characterization of treatment effects but are, by themselves, not sufficiently convincing to establish the main evidence in an application for a license or for an additional labeling claim."[4] Esperion, a sophisticated public company, was aware of this distinction when it designed the CLEAR Outcome Study, and it remains well aware of this distinction. DSE did not agree to pay Esperion $200-300 million for a 15% or greater relative risk reduction ("RRR") for a secondary endpoint, which on its own could never have materialized in an approved label. No rational pharmaceutical company would have in these circumstances.

Esperion's words and actions – both before and after execution of the Agreement – contradict its litigation position and confirm that it too understood the RRR component of the Regulatory Milestone Event was tied to the primary endpoint. From the start of its dialogue with DSE, Esperion focused on a **composite** endpoint of four major adverse cardiovascular events ("MACE-4"): nonfatal myocardial infarction, nonfatal stroke, death from cardiovascular causes, and coronary revascularization. Esperion (not DSE) designed the study at issue and Esperion (not DSE) strategically chose MACE-4 as the study's primary endpoint, choosing to designate the rest as secondary endpoints. Esperion also did everything it could **after** signing the Agreement to

[3] U.S. National Institutes of Health, *Glossary: National Center for Advancing Translational Sciences Toolkit for Patient Focused Therapy Development*, *available at* https://toolkit.ncats.nih.gov/glossary/endpoint/.

[4] *Evaluation of Medicines for Human Use*, The European Agency for the Evaluation of Medicinal Products (Sept. 19, 2002), *available at* https://www.ema.europa.eu/en/documents/scientific-guideline/points-consider-multiplicity-issues-clinical-trials_en.pdf.

achieve at least a 15% relative risk reduction ("RRR") for the MACE-4 primary endpoint, knowing a substantial payout would follow if the study results reached that threshold (and the regulator approved the requisite label set forth in the Agreement).

The Amended Complaint is replete with falsehoods, misleading statements, and inflammatory accusations. DSE responds generally to some of them here. First, Esperion claims it shared the "full" study results with DSE in "January 2023." (Am. Compl. ¶ 62). This is false. What Esperion "made available" in January 2023 was not the full study results. (Even if it was, Esperion also fails to explain why it waited more than two months after the study's completion on November 7, 2022 to share data with DSE, when the contract required Esperion to share it "promptly.") (Agreement, § 2.3.3). The record will show that Esperion slow-rolled the key data to DSE and tried to get DSE to commit to owing the Regulatory Milestone Payment before sharing the data DSE needed to determine if the RRR for the primary endpoint reached 15%. DSE had no direct visibility into the study or its results and had to rely on whatever piecemeal information Esperion was willing to share, which for months was virtually nothing.

Second, Esperion alleges that DSE "agreed to allow" Esperion to issue a press release in early January in which Esperion expressed a belief that it was entitled to receive a milestone payment from its collaboration partners in the U.S. and Europe. (Am. Compl. ¶¶ 60-61). Notably, at this time, Esperion had not provided DSE the data necessary to compute the RRR for the primary endpoint. Thus, DSE never "agreed" or even suggested the Regulatory Milestone Payment would be owed because DSE was still in the dark about the study results. Quite the opposite, DSE informed Esperion that it should not use DSE's name in any press release because: (1) DSE could not assess whether any Regulatory Milestone Payment might be due until Esperion shared the key data with DSE; and (2) Esperion, like any public company, is responsible for whatever it chooses

to tell its investors. When Esperion finally shared the data with DSE, DSE determined the RRR for the MACE-4 primary endpoint was no greater than 12.98%, well short of the Regulatory Milestone's 15% threshold requirement. Because the primary endpoint failed to reach 15%, DSE informed Esperion on March 14, 2023 that no regulatory milestone would be due irrespective of any approved label in Europe.

Esperion also mischaracterizes the drafting history of the Agreement. (*Id.* ¶¶ 37-42). The Regulatory Milestone Event includes (at least) two distinct requirements: (1) a 15% (or more) RRR in the study's primary MACE-4 endpoint (the main research question and most important outcome of the study); and (2) a corresponding approved "label" in Europe that includes cardiovascular risk reduction. The drafting history that Esperion highlights relates solely to the *second* element (*i.e.*, what the approved label needs to say), not the first element related to the threshold risk reduction. A quick reading of the exchanged drafts confirms they are not what Esperion makes them out to be, as they focus solely on the label and not on the risk reduction component.

Esperion also tries to blame DSE for the decrease in its stock price after Esperion publicly disclosed DSE's position on the regulatory milestone. (*Id.* ¶ 82). Esperion neglects to inform the Court what happened to its stock price immediately following Esperion's public disclosure of the study results in early March 2023, and before any public disclosure of the dispute with DSE. Based on Esperion's characterization of the "spectacular" data (*id*. at ¶ 6), one would have expected a positive market reaction to Esperion's release of the data results. Instead, Esperion's stock dropped **37.2%** between its disclosure of the study results and any public mention of its dispute with DSE.

On Friday, March 3, 2023, Esperion's stock closed at $6.34. The next day (Saturday, March 4), Esperion publicly disclosed the results of the CVOT for the first time at the American College of Cardiology ("ACC") conference in New Orleans, followed by a press conference the same day with Sheldon Koenig (Esperion's CEO). On the next trading day (Monday, March 6), Esperion's stock dropped to $5.08 (a one-day decrease of 19.9%). Over the next nine days, and before any public disclosure of the current dispute, Esperion's stock slid to $3.98 on March 15, 2023 – a 37.2% reduction following Esperion's March 4 disclosure of the study results. A similar drop also occurred in December 2022 when Esperion publicly disclosed the study's "top line" results.[5]

During this time, multiple articles noted the market's reaction to Esperion's release of the study results in March 2023. For example, one article noted that Esperion's "Outcomes win looks lacklustre," that a "13% reduction in the risk of cardiovascular events is statistically significant but not spectacular," and that "some had hoped for more."[6] These observations are consistent with the economic structure of the Agreement: while the study results demonstrated a statistically significant reduction in MACE-4 in statin intolerant patients, the reduction was not substantial enough to merit the large Regulatory Milestone Payment set forth in the Agreement.

Finally, Esperion's portrayal of DSE as a partner trying to exploit Esperion's financial condition is pure fiction. (Am. Compl. ¶ 12). There is zero evidence to support this allegation, which was absent from Esperion's original complaint drafted by other counsel. DSE has always

[5] Esperion alleges it announced the Study's top line results on December 7, 2022. Am. Compl. at ¶ 55. On December 6, 2022 (the previous day), Esperion's stock price closed at $7.44. On December 7 (immediately following Esperion's disclosure of the top line data), its stock closed at $6.33 (a 14.9% drop). By December 9 (two days later), it fell to $5.09 (a 31.6% drop from the December 6 close).

[6] Madeline Armstrong, *ACC 2023 – Esperion's Outcomes Win Looks Lacklustre*, Evaluate Vantage (March 4, 2023), https://www.evaluate.com/vantage/articles/events/conferences/acc-2023-esperions-outcomes-win-looks-lacklustre#:~:text=A%2013%25%20reduction%20in%20the,its%20cholesterol%2Dlowering%20pill%20Nexletol.

acted in good faith toward Esperion and has always honored, and will continue to honor, its obligations under the Agreement. DSE also remains committed to the parties' collaboration and the successful commercialization of the licensed products in territories that DSE controls, despite Esperion's tactics in this lawsuit. But DSE will not allow Esperion to rewrite the contract after-the-fact or collect a windfall to which the parties never agreed. Both New York contract law and any fair notion of justice prohibit such an outcome.

RESPONSES TO SPECIFIC PARAGRAPHS

Headings, sub-headings, and footnotes in the Amended Complaint do not constitute well-pleaded allegations of fact and therefore require no response. To the extent any response is required, DSE denies them. Unless expressly stated otherwise, DSE denies, generally and specifically, each and every allegation in the Amended Complaint, including any allegations in the introduction, unnumbered and numbered paragraphs, footnotes, titles and characterization of documents. DSE also specifically denies Esperion is entitled to its requested declaratory judgment or any other relief from DSE. To the extent not expressly denied, all allegations for which DSE lacks knowledge or information sufficient to form a belief are also denied. DSE reserves the right to amend or supplement its Answer as may be necessary. In response to the numbered paragraphs in the Amended Complaint, DSE states as follows:

1. DSE admits that DSE and Esperion entered into the Agreement in 2019 in which Esperion granted DSE an exclusive license to develop and commercialize bempedoic acid products in Switzerland and the European Economic Area in exchange for certain payments, certain contingent milestone payments and tiered royalties on net sales of bempedoic acid products. DSE denies that Esperion is entitled to any relief and denies the remaining allegations in Paragraph 1.

2. DSE admits that Esperion is based in the state of Michigan, that statins are a

common treatment for patients with high LDL cholesterol, and that certain patients around the world are "statin intolerant." DSE further admits that FDA and the European Medicines Agency ("EMA") have approved two of Esperion's products for commercial sale and with indications related to the reduction in LDL cholesterol. DSE denies the remaining allegations in Paragraph 2 because it lacks knowledge or information sufficient to form a belief as to their truth.

3. DSE admits that it is an affiliate of Daiichi Sankyo Company, Ltd., a pharmaceutical company based in Japan. DSE further admits that DSE and Esperion entered into the Agreement on January 2, 2019, and that DSE issued a press release announcing the Agreement. DSE admits that the quoted excerpts in Paragraph 3 appear in the DSE press release related to the Agreement, among other language. DSE also admits that when the parties executed the Agreement, the initial phases of the CLEAR Outcome Study, which Esperion was sponsoring, were underway. DSE admits that the primary efficacy endpoint and primary outcome measurement of the Clear Outcome Study was MACE-4, a composite of four major adverse cardiovascular events including cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, and coronary revascularization. DSE denies the remaining allegations in Paragraph 3.

4. DSE admits that Section 9.2 of the Agreement describes the requirements that must be met for Esperion to receive certain milestone payments from DSE, including a regulatory milestone payment that depends on the relative risk reduction percentage of the primary MACE-4 endpoint and whether a certain label is approved in Europe as set forth in the Agreement. DSE further admits that the quoted language in Paragraph 4 appears among other language in Section 9.2 of the Agreement, which is attached as Exhibit A to Esperion's First Amended Complaint. DSE denies the remaining allegations in Paragraph 4.

5. DSE admits that Esperion granted DSE an exclusive license to commercialize

bempedoic acid products in Switzerland and the European Economic Area in exchange for certain payments and certain contingent milestone payments, as well as tiered royalties on net sales of the bempedoic acid products. DSE further admits that at the time the parties executed the Agreement in January 2019, the initial phases of the CLEAR Outcome Study, which Esperion was sponsoring, were underway. DSE denies the remaining allegations in Paragraph 5 because it lacks knowledge or information sufficient to form a belief as to their truth.

6. DSE admits that it was informed that the CLEAR Outcome Study concluded in or around November 2022. Answering further, Paragraph 6 fails to differentiate between the primary and secondary endpoints of the CLEAR Outcome Study, the reduction percentages listed in Paragraph 6 appear to be rounded to whole percentage numbers, and certain of the reduction percentages listed in Paragraph 6 are of no or nominal significance. DSE denies the remaining allegations in Paragraph 6.

7. DSE admits that Esperion issued a press release on December 7, 2022 regarding the CLEAR Outcome Study and that Esperion presented results from the CLEAR Outcome Study at the ACC's annual conference on March 4, 2023. DSE further admits that an article summarizing the results of the CLEAR Outcome Study was published in the *New England Journal of Medicine.* DSE also admits that the International Lipid Expert Panel published a position paper regarding the use of bempedoic acid in March 2023. DSE denies the remaining allegations in Paragraph 7 because it lacks knowledge or information sufficient to form a belief as to their truth.

8. DSE admits that on March 8, 2023 it responded to Esperion's questions regarding the regulatory milestone and explained to Esperion that the CLEAR Outcome Study did not meet the requisite 15% relative risk reduction for the MACE-4 primary endpoint, one of the requirements to trigger the regulatory milestone. Answering further, DSE states that Esperion did

not share meaningful study data with DSE promptly but waited multiple weeks to do so. DSE denies the remaining allegations in Paragraph 8.

9. DSE denies the allegations in Paragraph 9. Answering further, DSE's position is fully consistent with the Agreement. DSE has always acted in good faith toward Esperion and paid Esperion all amounts due under the Agreement.

10. DSE admits that the term "cardiovascular risk reduction" is not a defined term in the Agreement. The remaining allegations in Paragraph 10 consist of legal conclusions for which no response is required. To the extent a response is required, DSE denies the allegations in Paragraph 10.

11. The allegations in Paragraph 11 consist of legal conclusions for which no response is required. To the extent a response is required, DSE denies the allegations in Paragraph 11.

12. DSE denies the allegations in Paragraph 12.

13. DSE denies the allegations in Paragraph 13. DSE has complied with its obligations at all times under the Agreement and will continue to do so. Esperion's stock price decreased more than 37% between Esperion's disclosure of the study results on March 4, 2023 at the ACC convention in New Orleans and Esperion's public disclosure of its contractual dispute with DSE.

14. DSE admits that Esperion seeks a judicial declaration in the Amended Complaint. DSE denies that Esperion is entitled to the $300 million regulatory milestone or any of the other relief it seeks, and therefore denies the remaining allegations in Paragraph 14.

15. DSE admits that Esperion is incorporated in the State of Delaware and has its principal place of business in Ann Arbor, Michigan. DSE further admits that Esperion is publicly traded on the NASDAQ exchange under the ticker symbol "ESPR." DSE also admits Esperion has developed and commercialized medicines for patients with elevated LDL cholesterol. DSE

denies the remaining allegations in Paragraph 15 because it lacks knowledge or information sufficient to form a belief as to their truth.

16. DSE admits that it is a limited liability company organized under the laws of Germany with its principal place of business in Munich, Germany. DSE further admits that it is a wholly owned affiliate of Daiichi Sankyo Company, Ltd., which is headquartered in Tokyo, Japan. DSE further admits that Daiichi Sankyo, Inc. and American Regent, Inc. are U.S.-based affiliates of Daiichi Sankyo Company, Ltd.

17. The allegations in Paragraph 17 consist of legal conclusions for which no response is required.

18. The allegations in Paragraph 18 consist of legal conclusions for which no response is required.

19. DSE admits venue in this District is proper as the parties consented in the Agreement.

20. DSE admits that Esperion has sought the approval of two drug therapies containing bempedoic acid. DSE further admits that bempedoic acid has been approved by FDA "as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C." DSE denies the remaining allegations in Paragraph 20 because it lacks knowledge or information sufficient to form a belief as to their truth.

21. DSE admits the allegations in Paragraph 21.

22. DSE admits that statins are often the first line of treatment for patients with high LDL cholesterol and there is an unmet need for patients with high LDL cholesterol who cannot tolerate statins. DSE further admits that statins are oral pharmaceuticals that are biologically active

throughout the body. DSE further admits that the publication that Esperion cites at Footnote 2 in the Amended Complaint states that evidence suggests more than 4 million patients in the U.S. may be statin intolerant. DSE denies the remaining allegations in Paragraph 22 because it lacks sufficient knowledge or information to form a belief as to their truth.

23. DSE admits the allegations in Paragraph 23.

24. DSE admits that a tablet containing bempedoic acid was approved by the FDA as Nexletol® in 2020 and by the European Medicines Agency ("EMA") as Nilemdo® in 2020. DSE further admits that a tablet containing a combination of bempedoic acid and ezetimibe was approved by the FDA as Nexlizet® and by the EMA as Nustendi® in 2020. DSE admits these treatments are marketed and sold in the U.S., the European Economic Territory and Switzerland. DSE denies any remaining allegations in Paragraph 24.

25. DSE admits the allegations in Paragraph 25.

26. DSE admits the allegations in Paragraph 26.

27. DSE admits that, according to the Clinical Study Report for the CLEAR Outcome Study, the study started in November 2016 and concluded in November 2022. DSE further admits that, according to the study protocol, the CLEAR Outcome Study was a randomized, double-blind, placebo-controlled study designed to assess if treatment with bempedoic acid versus placebo decreases the risk of cardiovascular events in patients who are statin intolerant. DSE further admits that, according to the Clinical Study Report for the CLEAR Outcome Study, over 13,900 patients were analyzed in the CLEAR Outcome Study. DSE denies the remaining allegations in Paragraph 27 as it lacks sufficient knowledge and information to form a belief as to their truth.

28. DSE admits that MACE-4, a composite of four major adverse cardiovascular events including cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, and coronary

revascularization, was the "primary efficacy endpoint" of the CLEAR Outcome Study. DSE further admits that the CLEAR Outcome Study had multiple secondary endpoints in addition to the main, primary MACE-4 endpoint. DSE denies the remaining allegations in Paragraph 28.

29. DSE admits that Esperion explored a partnership to commercialize and sell its bempedoic acid products in Europe and that DSE and Esperion discussed such a partnership and ultimately negotiated a definitive agreement. DSE denies the remaining allegations in Paragraph 29 because it lacks sufficient knowledge or information to form a belief as to their truth.

30. DSE denies the allegations in Paragraph 30 because it lacks sufficient knowledge or information to form a belief as to their truth.

31. DSE admits that it sent Esperion a Statement of Interest dated November 8, 2018 with a proposal that would grant DSE an exclusive license to develop and commercialize bempedoic acid products in Switzerland and the European Economic Area in exchange for various payments (including a contingent regulatory milestone payment) and tiered royalties on net sales of bempedoic acid products. DSE denies the remaining allegations in Paragraph 31.

32. DSE admits that the quoted language and chart in Paragraph 32 appears among other language in the Statement of Interest dated November 8, 2018 that DSE sent to Esperion. DSE denies the remaining allegations in Paragraph 32.

33. The allegations in Paragraph 33 consist of legal conclusions for which no response is required. To the extent a response is required, DSE denies the allegations in Paragraph 33. Answering further, Esperion ignores any distinction between the Study's MACE-4 primary endpoint and the various secondary endpoints. The parties understood and agreed, during negotiations and at the time they executed the Agreement, that the relative risk reduction component of the regulatory milestone was tied to the Study's MACE-4 primary endpoint and not

to any of the secondary endpoints.

34. DSE admits that DSE and Esperion entered into an exclusivity agreement on November 19, 2018. DSE denies the remaining allegations in Paragraph 34 because it lacks knowledge or information sufficient to form a belief as to their truth.

35. DSE admits the allegations in Paragraph 35.

36. DSE admits that on November 19, 2018 Esperion sent a draft of the Agreement to DSE. DSE further admits that the quoted language and the chart in Paragraph 36 appears in a November 19, 2018 draft of the Agreement, among other language. DSE also admits that the draft did not define the term "Cardiovascular Risk Reduction." DSE denies the remaining allegations in Paragraph 36.

37. DSE admits that on November 30, 2018 DSE through counsel sent a draft of the Agreement to Esperion. DSE further admits that the quoted language and the chart in Paragraph 37 appear in a November 30, 2018 draft of the Agreement, among other language. DSE denies the remaining allegations in Paragraph 37.

38. DSE admits that the quoted language in Paragraph 38 appears in a November 30, 2018 draft of the Agreement, among other language. DSE further admits that at the time the parties were negotiating in November 2018, DSE understood that the CLEAR Outcome Study had already begun. DSE denies the remaining allegations in Paragraph 38.

39. DSE denies the allegations in Paragraph 39.

40. DSE denies the allegations in Paragraph 40.

41. DSE admits that on December 11, 2018 Esperion sent DSE a revised draft of the Agreement. DSE further admits that the quoted language in Paragraph 41 appears in a December 11, 2018 draft of the Agreement, among other language. DSE denies the remaining allegations in

Paragraph 41.

42. DSE denies the allegations in Paragraph 42.

43. DSE admits the allegations in Paragraph 43.

44. DSE admits the quoted language in Paragraph 44 appears in Sections 1.77 and 4.1 of the Agreement, among other language, and that the Licensed Products include Nilemdo® and Nustendi®. The remaining allegations in Paragraph 44 consist of legal conclusions for which no response is required. To the extent a response is required, DSE denies the allegations in Paragraph 44.

45. DSE admits that Section 9 of the Agreement includes the financial terms of the Agreement, including the contingent milestone payments, their requirements, and the tiered royalty structure based on net sales. DSE denies the remaining allegations in Paragraph 45.

46. DSE admits that the quoted language in Paragraph 46 appears in Section 9.2 of the Agreement, among other language. DSE denies the remaining allegations in Paragraph 46.

47. DSE admits the Agreement does not define "cardiovascular risk reduction." DSE denies the remaining allegations in Paragraph 47.

48. DSE admits the quoted language in Paragraph 48 appears in Section 9.2 of the Agreement, among other language, and that the requirements for the Regulatory Milestone Payment include (1) a certain approved label in Europe as set forth in the Agreement; and (2) a minimum of a 15% relative risk reduction for the primary MACE-4 endpoint. DSE denies the remaining allegations in Paragraph 48.

49. DSE admits that the quoted chart in Paragraph 49 appears in Section 9.2 of the Agreement, among other language. The Regulatory Milestone Payment was contingent on the study results and not a foregone conclusion that it would be paid to Esperion. DSE denies the

remaining allegations in Paragraph 49.

50. DSE admits that the quoted language in Paragraph 50 appears in Section 9.2 of the Agreement, among other language. DSE denies the remaining allegations in Paragraph 50.

51. DSE admits that Esperion issued a press release on January 4, 2019 announcing the Agreement, which DSE reviewed prior to its issuance, and that the quoted language in Paragraph 51 appears among other language in the press release cited in Footnote 7 of the Amended Complaint. DSE denies the remaining allegations in Paragraph 51.

52. DSE admits that it issued a press release on January 7, 2019 announcing the Agreement and that the quoted language in Paragraph 52 appears in the press release cited in Footnote 8 of the Amended Complaint, among other language. DSE denies the remaining allegations in Paragraph 52.

53. DSE admits that in 2020 Esperion transferred the European Marketing Authorization for Nilemdo® and Nustendi® to DSE. DSE further admits that it began marketing and selling Nilemdo® and Nustendi® in Germany in 2020, in the U.K. and Austria in 2021, in Belgium and Switzerland in 2022, and Italy in 2023. DSE also admits that Esperion is responsible for the development of products, including clinical trials, under the Agreement and that DSE is responsible for commercializing the products in Switzerland and the European Economic Territory. DSE denies the remaining allegations in Paragraph 53.

54. DSE admits that, according to the Clinical Study Report for the CLEAR Outcome Study, the Study concluded in November 2022. DSE further admits that, based on the data it has received from Esperion, the Study results showed that patients treated with bempedoic acid had a reduced risk of certain adverse cardiovascular events. Paragraph 54 fails to differentiate between the primary and secondary endpoints of the CLEAR Outcome Study. It also fails to state that the

reduction percentages listed in Paragraph 54 appear to be rounded to whole percentage numbers, that certain of the rounded risk reduction percentages listed in Paragraph 54 are of no or nominal statistical significance, and that certain patient data has been censored. DSE denies the remaining allegations in Paragraph 54 because it lacks sufficient knowledge and information to form a belief as to their truth.

55. DSE admits that on December 7, 2022 Esperion issued a press release regarding results of the CLEAR Outcome Study and that the quoted language in Paragraph 55 appears in the press release referred to in Footnote 9 of the Amended Complaint, among other language. DSE denies the remaining allegations in Paragraph 55.

56. DSE admits the quoted language in Paragraph 56 appears among other language in an email sent by Dr. Wolfgang Schiessel, Senior Director, PR & Portfolio Communications, Specialty Medicines at DSE, to Esperion on or around December 7, 2022 and before Esperion shared any data with DSE that would allow DSE to compute any risk reduction percentages for the primary endpoint (or any endpoint) of the Study. DSE denies the remaining allegations in Paragraph 56.

57. DSE admits that on December 8, 2022 DSE issued a press release regarding results of the CLEAR Outcome Study and that the quoted language in Paragraph 57 appears in the press release cited in Footnote 10 of the Amended Complaint, among other language. At the time of the press release, Esperion had not yet provided DSE sufficient data for DSE to assess the risk reduction percentages of the primary endpoint or any other endpoint of the study. DSE denies the remaining allegations of Paragraph 57.

58. DSE admits the quoted language in Paragraph 58 appears in the press release cited in Footnote 10 of the Amended Complaint, among other language. DSE denies the remaining

allegations in Paragraph 58.

59. DSE admits that the quoted language in Paragraph 59 appears in an email sent by Sheldon Koenig, the current Chief Executive Officer of Esperion, to Dr. Jan Van Ruymbeke, the Chief Executive Officer of DSE on December 11, 2022, among other language. DSE denies the remaining allegations in Paragraph 59.

60. DSE admits the quoted language in Paragraph 60 appears in an email sent by Benjamin Looker, General Counsel at Esperion, on or around December 16, 2022 to Dr. Philipp Hoffman, Executive Director, Business Development & Licensing, at DSE, among other language. Esperion at the time had not yet provided DSE sufficient data from the study to enable DSE to evaluate or compute any risk reduction percentage for the primary endpoint (or any other endpoint). DSE denies the remaining allegations in Paragraph 60, including that DSE "agreed to allow" Esperion to issue a press release.

61. DSE admits the quoted language in Paragraph 61 appears in the press release referred to in Footnote 11 of the Amended Complaint, among other language. DSE denies the remaining allegations in Paragraph 61.

62. The Agreement required Esperion to share "promptly" with DSE all study data, including any patient level data. (Agreement, § 2.3.3). Esperion did not comply with this obligation. After several weeks of urging Esperion to comply with its obligation, DSE admits that Esperion agreed to make certain limited information from the CLEAR Outcome Study available to a small number of DSE employees. Esperion insisted that each DSE employee sign a new confidentiality agreement, even though the Agreement itself already contained substantial protection for Esperion that any data shared would remain confidential. The limited information that Esperion shared on or around January 20, 2023 consisted of "top line" results presented

remotely in a PowerPoint presentation and did not include any meaningful information about the primary MACE-4 endpoint or any patient-level detail data as required under the Agreement. DSE denies the remaining allegations in Paragraph 62 because it lacks knowledge or information sufficient to form a belief as to their truth.

63. DSE admits that on January 20, 2023 DSE and Esperion participated in a remote video conference during which Esperion presented several slides from a PowerPoint presentation. However, the presentation did not satisfy Esperion's data-sharing obligations under the Agreement. The presentation did not include patient level data as required by the Agreement. It also failed to include any meaningful information about the primary MACE-4 endpoint, which Dr. Foody acknowledged. DSE denies the remaining allegations in Paragraph 63.

64. DSE admits that on February 15, 2023, DSE asked again for Esperion to provide patient-level data regarding the CLEAR Outcome Study, which Esperion still had not provided to DSE even though Section 2.3.3 of the Agreement required Esperion to produce "patient level data" "promptly." DSE needed this information to assess the relative risk reduction percentage for the primary endpoint. DSE admits that Esperion finally sent DSE patient level data after repeated requests to do so. DSE denies the remaining allegations in Paragraph 64.

65. DSE admits that results of the CLEAR Outcome Study were published in the *New England Journal of Medicine* on March 4, 2023 and that the quoted language in Paragraph 65 appears in that publication, among other language. DSE further admits that Esperion also presented study results to the American College of Cardiology conference on March 4, 2023. DSE denies the remaining allegations in Paragraph 65.

66. DSE admits that the CLEAR Outcome Study was reported on in certain publications, including *The New York Times, The Wall Street Journal and The Washington Post*.

DSE denies the remaining allegations in Paragraph 66 because it lacks knowledge or information sufficient to form a belief as to their truth.

67. DSE admits that the quoted language in Paragraph 67 appears, among other language, in a *New England Journal of Medicine* editorial published on March 4, 2023. DSE also admits that the quoted language in Paragraph 67 appears, among other language, in a Cleveland Clinic article published on March 4, 2023. DSE further admits that the International Lipid Expert Panel published a recommendation regarding the use of bempedoic acid in the management of lipid disorders and cardiovascular risk on March 7, 2023, following the publication of results from the CLEAR Outcome Study. DSE denies the remaining allegations in Paragraph 67 because it lacks knowledge or information sufficient to form a belief as to their truth.

68. DSE denies the allegations in Paragraph 68 because it lacks knowledge or information sufficient to form a belief as to their truth.

69. DSE admits that on March 4, 2023, Esperion issued a press release and that the quoted language in Paragraph 69 appears in that press release, among other language. DSE denies the remaining allegations in Paragraph 69.

70. DSE admits that the quoted language in Paragraph 70 appears among other language in an email sent by Andreas Berger, Senior Director, Regional Management at DSE, to Esperion on or around March 8, 2023. DSE denies the remaining allegations in Paragraph 70.

71. DSE admits that the quoted language in Paragraph 71 appears in an email sent by Esperion to DSE on March 8, 2023. DSE denies the remaining allegations in Paragraph 71.

72. DSE denies it reneged on its contractual commitment. DSE admits the quoted language in Paragraph 72 appears among other language in an email sent by Andreas Berger, Senior Director, Regional Management at DSE, to Ms. Vanston at Esperion. DSE denies the

remaining allegations in Paragraph 72.

73. DSE denies the allegations in Paragraph 73.

74. DSE admits that the quoted language in Paragraph 74 appears among other langue in an email sent by Benjamin Looker, Esperion's General Counsel, to DSE. DSE denies the remaining allegations in Paragraph 74.

75. DSE admits that on March 15, 2023 Mr. Berger replied to the email sent by Mr. Looker on March 14, 2023. DSE denies the remaining allegations in Paragraph 75.

76. DSE admits that Sheldon Koenig, Chief Executive Officer at Esperion, and Dr. Jan Van Ruyembeke, Chief Executive Officer at DSE, spoke by telephone on March 20, 2023 and March 22, 2023. DSE denies the remaining allegations in Paragraph 76.

77. In response to Paragraph 77, DSE incorporates by reference its response to Paragraph 54. The remaining allegations in Paragraph 77 consist of legal conclusions for which no response is required. To the extent a response is required, DSE denies the allegations in Paragraph 77.

78. DSE denies the allegations in Paragraph 78.

79. The allegations in Paragraph 79 are irrelevant to Esperion's claims and many lack any factual basis. DSE denies that it or its parent "recently faced uncertain business prospects and significant financial pressure." DSE further denies that "it was only a matter of time" before Esperion earned the Regulatory Milestone Payment. The Regulatory Milestone Payment was always contingent and dependent in part on whether the CLEAR Outcome Study results showed at least a 15% relative risk reduction for the composite MACE-4 primary endpoint, which they did not. DSE admits that in 2019 an affiliate received a Complete Response Letter from FDA regarding the New Drug Application for quizartinib for the treatment of adults with

relapsed/refractory FLT3-ITD acute myeloid leukemia (AML) and that FDA notified DSE's affiliate in October 2022 that FDA extended the review period for quizartinib by three months. No additional efficacy or safety data has been requested by FDA. DSE's parent and/or its affiliates have successfully developed and brought to market a substantial number of products that have helped patients around the world across multiple therapeutic areas. The development of quizartinib has nothing to do with this case and Esperion's failure to earn the Regulatory Milestone Payment under the Agreement. DSE denies the remaining allegations in Paragraph 79.

80. DSE admits that Esperion has certain obligations to its shareholders as a publicly traded company. DSE denies the remaining allegations in Paragraph 80.

81. DSE admits that the quoted language in Paragraph 81 appears in a Form 8-K filed by Esperion on March 15, 2023 and cited in Footnote 13 of the Amended Complaint, among other language. The allegations regarding DSE's contractual obligations and Esperion's obligations under the securities laws are legal conclusions for which no response is required. To the extent a response is required, DSE denies those allegations in Paragraph 81. DSE denies the remaining allegations in Paragraph 81.

82. DSE admits that Esperion's stock price has been in decline since Esperion publicly announced the CLEAR Outcome Study results on March 4, 2023 at the ACC. DSE denies the remaining allegations in Paragraph 82.

83. DSE denies the allegations in Paragraph 83. DSE further states that the allegations regarding DSE's contractual obligations are legal conclusions for which no response is required. To the extent a response is required, DSE denies those allegations in Paragraph 83. DSE denies the remaining allegations in Paragraph 83 because it lacks knowledge or information sufficient to form a belief as to their truth.

84. DSE denies the allegations in Paragraph 84.

85. In response to Paragraph 85, DSE restates and incorporates here its responses to Paragraphs 1 through 84.

86. The allegations in Paragraph 86 consist of legal conclusions for which no response is required. To the extent a response is required, DSE denies the allegations in Paragraph 86.

87. DSE admits that DSE and Esperion entered into the Agreement on January 2, 2019. DSE further admits that Esperion granted DSE an exclusive license to develop and commercialize bempedoic acid products in Switzerland and the European Economic Area in exchange for consideration, including an upfront cash payment, various contingent milestone payments and tiered royalties on net sales of bempedoic acid products. DSE denies the remaining allegations in Paragraph 87.

88. The allegations in Paragraph 88 consist of legal conclusions for which no response is required. To the extent a response is required, DSE denies the allegations in Paragraph 88.

89. DSE admits that the quoted language in Paragraph 89 appears in Section 9.2 of the Agreement, among other language. The remaining allegations in Paragraph 89 consist of legal conclusions for which no response is required. To the extent a response is required, DSE denies the remaining allegations in Paragraph 89.

90. In response to Paragraph 90, DSE incorporates by reference its response to Paragraph 54. DSE denies the remaining allegations in Paragraph 90 and that any of the cited percentages were sufficient to achieve the Regulatory Milestone Payment.

91. In response to Paragraph 91, DSE incorporates by reference its response to Paragraph 54. DSE denies the remaining allegations in Paragraph 91 and that any of the cited percentages were sufficient to achieve the Regulatory Milestone Payment.

92. The allegations in Paragraph 92 consist of legal conclusions for which no response is required. To the extent a response is required, DSE denies the allegations in Paragraph 92 and that any of the cited percentages were sufficient to achieve the Regulatory Milestone Payment.

93. DSE denies the allegations in Paragraph 93 and that any of the cited percentages were sufficient to achieve the Regulatory Milestone Payment.

94. DSE admits that because the CLEAR Outcome Study did not achieve a 15% relative risk reduction for MACE-4, the primary endpoint, Esperion is not entitled to any Regulatory Milestone Payment under Section 9.2 of the Agreement. DSE denies the remaining allegations in Paragraph 94.

95. The allegations in Paragraph 95 consist of legal conclusions for which no response is required. To the extent a response is required, DSE denies the allegations in Paragraph 95.

96. The allegations in Paragraph 96 regarding the Agreement consist of legal conclusions for which no response is required. To the extent a response is required, DSE denies the allegations in Paragraph 96. DSE denies the remaining allegations in Paragraph 96.

97. The allegations in Paragraph 97 consist of legal conclusions for which no response is required. To the extent a response is required, DSE denies the allegations in Paragraph 97.

98. DSE admits that the parties have been reviewing a draft submission to the European Medicines Agency regarding the bempedoic acid products related to the CLEAR Outcome Study. The remaining allegations in Paragraph 98 consist of legal conclusions for which no response is required. To the extent a response is required, DSE denies the remaining allegations in Paragraph 98.

99. The allegations in Paragraph 99 consist of legal conclusions for which no response is required. To the extent a response is required, DSE denies the allegations in Paragraph 99.

100. DSE admits that Esperion's stock price has been in decline since Esperion announced the CLEAR Outcome Study results on March 4, 2023. The remaining allegations in Paragraph 100 consist of legal conclusions for which no response is required. To the extent a response is required, DSE denies the remaining allegations in Paragraph 100.

101. The allegations in Paragraph 101 consist of legal conclusions for which no response is required. To the extent a response is required, DSE denies the allegations in Paragraph 101.

102. The allegations in Paragraph 102 consist of legal conclusions for which no response is required. To the extent a response is required, DSE denies the allegations in Paragraph 102.

103. The allegations in Paragraph 103 consist of legal conclusions for which no response is required. To the extent a response is required, DSE denies the allegations in Paragraph 103.

104. The allegations in Paragraph 104 consist of legal conclusions for which no response is required. To the extent a response is required, DSE denies the allegations in Paragraph 104.

105. The allegations in Paragraph 105 consist of legal conclusions for which no response is required. To the extent a response is required, DSE denies the allegations in Paragraph 105.

106. DSE denies the allegations in Paragraph 106.

107. DSE denies the allegations in Paragraph 107.

108. DSE denies the allegations in Paragraph 108.

ANSWER TO PRAYER FOR RELIEF

DSE denies that Esperion is entitled to any of the relief sought in its Prayer for Relief. As to Esperion's requested declarations, the Court should reject each and every request and instead declare the opposite as set forth in DSE's Prayer for Relief.

* * * *

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), DSE demands a trial by jury of all issues so triable.

AFFIRMATIVE DEFENSES

DSE affirmatively states that Esperion is not entitled to any relief on its Complaint. DSE further asserts the following affirmative defenses, without conceding that DSE bears the burden of production or persuasion as to any of them. In support of its Affirmative Defenses, DSE incorporates by reference the "General Response and Statement of Facts in Support of DSE's Affirmative Defenses" as if fully set forth herein.

FIRST AFFIRMATIVE DEFENSE
(Failure to State A Claim)

Esperion has failed to provide a reasonable statement of a claim for relief against DSE. DSE does not have reasonable notice of the time, place, nature, and manner of the claimed wrongs by DSE as they relate to Esperion's alleged injuries. Therefore, Esperion has failed to state a claim against DSE upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE
(Estoppel)

Esperion's claims against DSE are barred in whole or in part by the doctrine of estoppel.

THIRD AFFIRMATIVE DEFENSE
(Unclean Hands)

Esperion's claims for a declaratory judgment against DSE are barred because Esperion has intentionally engaged in misconduct toward DSE, designed to increase the appearance of harm.

* * * *

DSE reserves the right to add to its affirmative defenses as additional information becomes available in the course of this litigation.

DSE'S PRAYER FOR RELIEF

WHEREFORE, DSE requests the following relief:[7]

1) That Esperion's request for relief in the Amended Complaint be denied in its entirety;

2) That Esperion's requests for declaratory judgment in the Amended Complaint be denied in their entirety and that the Court instead declare the below:

   a. that the phrase "the relative risk reduction rate indicated below as a result of the CLEAR Outcome Study" as used in Section 9.2 of the Agreement refers solely to the relative risk reduction rate of the composite MACE-4 primary endpoint in the CLEAR Outcome Study;

   b. that the phrase "the relative risk reduction rate indicated below as a result of the CLEAR Outcome Study" as used in Section 9.2 of the Agreement does not refer to a risk reduction rate of any secondary endpoint of the CLEAR Outcome Study, including without limitation the risk of nonfatal myocardial infarction (heart attacks), the composite of nonfatal and fatal myocardial infraction, fatal and nonfatal stroke, coronary revascularization, and MACE-3 as reported in the CLEAR Outcome Study;

   c. that any reduction in the risk of nonfatal myocardial infarction and/or the composite of nonfatal and fatal myocardial infraction (both secondary endpoints) greater than 20% in patients using bempedoic acid in the CLEAR Outcome Study does not entitle Esperion to a $300 million Regulatory Milestone Payment, upon Regulatory Approval of an amended label including cardiovascular risk reduction;

[7] DSE acknowledges that this Court has found that in actions for declaratory relief, counterclaims that state the opposite or request a "mirror image" declaration are unnecessary. *Bodum Holding AG v. Starbucks Corp.*, No. 19 CIV. 4280 (ER), 2020 WL 6135714, at *1, *11 (S.D.N.Y. Oct. 16, 2020). For this reason, DSE does not assert a counterclaim but rather presents its requested declaratory relief in its Prayer for Relief.

d. that any reduction in the risk of fatal and nonfatal stroke, coronary revascularization, and/or MACE-3 (all secondary endpoints) equal to or greater than 15% and less than 20% in patients using bempedoic acid in the CLEAR Outcome Study does not entitle Esperion to a $200 million Regulatory Milestone Payment, upon Regulatory Approval of an amended label including cardiovascular risk reduction; and

e. that any reduction in the risk of the MACE-3 secondary endpoint in the CLEAR Outcome Study did not achieve 15%.

3) An award of attorneys' fees, costs, and disbursements; and

4) Any other and further relief as the Court may deem just and appropriate.

Dated: June 20, 2023

Respectfully submitted,

/s/ Toni-Ann Citera

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Attorneys for Defendant Daiichi Sankyo Europe GmbH

CERTIFICATE OF SERVICE

I hereby certify that on June 20, 2023, I caused the foregoing Defendant Daiichi Sankyo Europe GmbH's Answer and Affirmative Defenses to Esperion's First Amended Complaint to be filed with the Clerk of the Court and served upon all counsel of record via the Court's CM/ECF system.

/s/ Toni-Ann Citera
Toni-Ann Citera